

VIRGINIA DEPARTMENT OF HEALTH

Office of Licensure and Certification

Division of Certificate of Public Need

Staff Analysis

July 20, 2026

COPN Request No. VA-8885

James River Cardiology, LLC d/b/a AlignedCardio

Salem, Virginia

Establish a Center for PET/CT services with one fixed PET/CT scanner limited to cardiology

Applicant

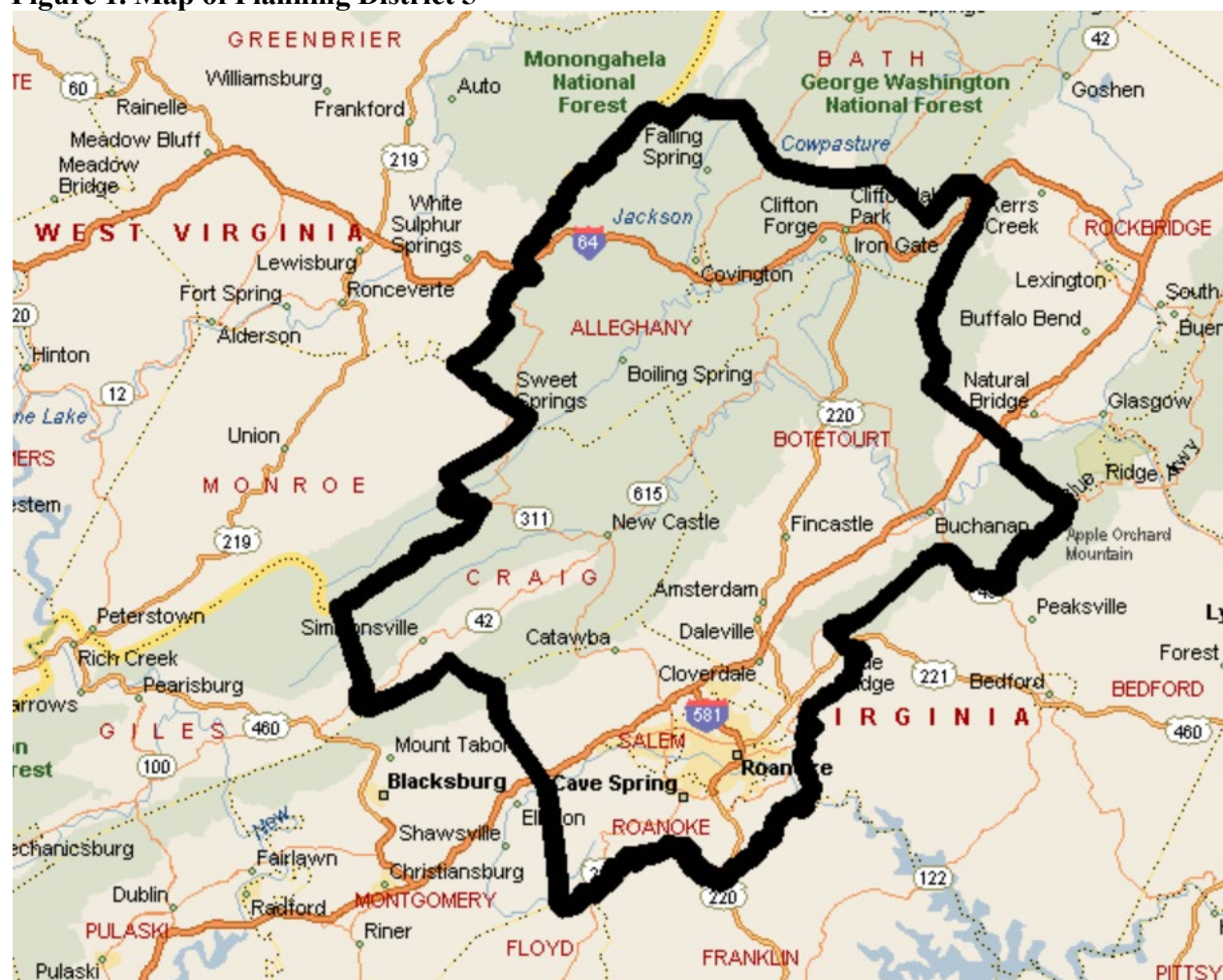
James River Cardiology, LLC (“JRC”) is a limited liability company formed under the laws of Delaware. Although originally formed as a Professional Corporation (P.C.) in 2010, it was converted to a Limited Liability Company (LLC) in 2023. JRC is a wholly owned subsidiary of Cavalier MSO, LLC. The proposed facility, Southwest Virginia Cardiology, a practice of James River Cardiology, LLC d/b/a AlignedCardio (“AlignedCardio”) is in leased space at 2850 Keagy Road, Salem, Virginia, in PD 5, HPR III.

Background

PD 5 is in Southwest Virginia, bordering West Virginia to the west. It includes the counties of Alleghany, Botetourt, Craig, Roanoke and the independent Cities of Covington, Craig, Roanoke and Salem (**Figure 1**). PD 5 is relatively rural, and travel is difficult in parts of PD 5, due to mountainous terrain. PD 5 had a population of 281,734 in 2020 that is projected to decrease by 3,813 people (1.4% decrease) between 2020 and 2030. In comparison, the population change projected for Virginia during this decade is an increase of 5.0%. The City of Salem, the locality where the proposed project is located, is projected to decrease by 1.9% (486 people) between 2020 and 2030 (**Table 1**). The older population is an important segment for the proposed project, as those aged 65 and older have a significantly higher risk of coronary artery disease.¹ The growth rates projected for 2020-2030 in the 65 and older age group are 18.7% in the City of Salem and 18.3% in PD 5, compared to 30.9% across Virginia (**Table 1**).

¹ <https://www.ahajournals.org/doi/10.1161/CIR.0000000000001387#:~:text=1,can%20exacerbate%20aggregate%20prognostic%20risk.>

Figure 1. Map of Planning District 5



Source: Microsoft Streets & Trips

Table 1. PD 5 Population Data

Location	2020 Population	2030 Population	Growth 2020- 2030	Percent Growth 2020-2030	65+ 2020 Population	65+ 2030 Population	Growth 65+	Percent Growth 65+
Allegheny County	15,223	14,295	-928	-6.1%	3,933	4,207	274	7.0%
Botetourt County	33,596	33,047	-549	-1.6%	7,882	9,529	1,647	20.9%
Craig County	4,892	4,539	-353	-7.2%	1,124	1,280	156	13.9%
Roanoke County	96,929	96,811	-118	-0.1%	21,449	25,495	4,046	18.9%
City of Covington	5,737	5,282	-455	-7.9%	1,201	1,316	115	9.6%
City of Roanoke	100,011	99,086	-925	-0.9%	17,899	21,439	3,540	19.8%
City of Salem	25,346	24,860	-486	-1.9%	5,328	6,325	997	18.7%
PD 5	281,734	277,921	-3,813	-1.4%	58,816	69,591	10,775	18.3%
Virginia, Statewide	8,631,393	9,060,433	429,040	5.0%	1,395,291	1,826,064	430,773	30.9%

Source: Weldon-Cooper Center for Public Service (2026)

PET/CT Services

A positron emission tomography (PET) scan is an imaging test that can help reveal the metabolic or biochemical function of tissues and organs. The PET scan uses a radioactive drug called a tracer to show both typical and atypical metabolic activity. A PET scan can often detect the atypical metabolism of the tracer in diseases before the disease shows up on other imaging tests, such as computerized tomography (CT) and magnetic resonance imaging (MRI). The tracer is most often injected into a vein in the hand or arm. The tracer will then collect in areas of the body that have higher levels of metabolic or biochemical activity. This often pinpoints the location of the disease. The PET images are typically combined with CT or MRI and are called PET/CT or PET/MRI scans.² Note from the State Medical Facilities Plan (SMFP): For the purposes of tracking volume utilization, an image taken with a PET/CT scanner that takes concurrent PET/CT images shall be counted as one PET procedure. Images made with PET/CT scanners that can take PET or CT images independently shall be counted as one individual PET procedure and one CT procedure, respectively, unless those images are made concurrently. The applicant has stated that the CT component of the proposed PET/CT scanner will only be used concurrently with PET imaging.

JRC's COPN Request No. VA-8885 proposes a PET/CT service limited to cardiac imaging. Of particular relevance to JRC's proposal, PET/CT has emerged as the standard of care for myocardial perfusion, recommended by the Centers for Medicare & Medicaid Services (CMS),³ the American Society of Nuclear Cardiology (ASNC) and the Society of Nuclear Medicine and Molecular Imaging (SNMMI).⁴ Despite single-photon emission computerized tomography (SPECT) being the most used nuclear imaging technique for the diagnosis of coronary artery disease (CAD), many now consider PET as a superior modality due to higher resolution, greater diagnostic accuracy and lower radiation exposure.⁵ This transition from cardiac SPECT has contributed to rapid growth in PET imaging in recent years.⁶

Regarding cardiac PET, the American Society of Nuclear Cardiology and the Society of Nuclear Medicine and Molecular Imaging published a joint position paper in 2016 (Society Joint Position Statement) stating:

The purpose of this joint Society Position Statement is to highlight the attributes that make rest/stress myocardial perfusion PET both **Preferred** and **Recommended** in the era of high value initiatives for appropriate patients. Myocardial perfusion PET image quality, high diagnostic accuracy that is relatively independent of body habitus, ability to accurately risk stratify patients with a wide array of clinical presentations, short acquisition times, safety by virtue of low radiation exposure, and its unique ability to quantify myocardial blood flow are all significant and clinically important properties. The properties of myocardial perfusion PET according to the published literature are sufficient to advance recommendations for its use in clinical practice. There are no clinical scenarios where PET should not be considered a

²<https://www.mayoclinic.org/tests-procedures/pet-scan/about/pac-20385078>

³ <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCID=292&NCDver=2>

⁴ <https://www.asnc.org/files/Guidelines%20and%20Quality/PET%20GuidelineASNC%20SNMMI2016.pdf>

⁵<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10170052/#:~:text=High%20Resolution&text=PET%20provides%20a%20substantial%20advantage,in%20PET%20vs%20SPECT%20machines.>

⁶ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10170052/>

preferred test for patients who meet appropriate criteria for a stress imaging test and who require pharmacologic stress.⁷

According to Virginia Health Information (VHI) data for 2024, the latest year for which such data are available, PD 5 had two PET services in operation that year with three fixed site scanners (**Table 2**). No additional PET scanners have been authorized in PD 5 since 2024, so the three PET scanners in **Table 2** represent the full current inventory of PET scanners in PD 5.

Table 2. Utilization of PD 5 PET Scanners, 2024

Facility Name	Scanners	Procedures	Procedures per Scanner	% of SMFP Threshold
Carilion Roanoke Memorial Hospital	2	4,315	2,158	36.0%
LewisGale Medical Center	1	962	962	16.0%
PD 5 Totals and Average	3	5,277	1,759	29.3%

Source: 2024 VHI

Proposed Project

JRC proposes to establish a cardiac PET service with one PET/CT scanner in leased space at 2850 Keagy Road, Salem, Virginia, which is the current location of the existing Southwest Virginia Cardiology practice, a division of JRC. The applicant has stated that it will not use the CT component of the equipment independently but will only perform PET/CT scans, restricted to cardiac use. Among a full range of outpatient cardiovascular services, JRC currently offers nuclear cardiology, including SPECT myocardial perfusion imaging (not regulated by COPN). Underlying the proposed project is the conversion of its existing SPECT services to PET imaging for appropriate patients, as PET is now considered the superior modality for myocardial perfusion imaging in most cases. The applicant states that the proposal will require only minor interior modifications to the building to accommodate installation of the PET/CT scanner.

The projected capital costs of the proposed project are \$1,178,085 (**Table 3**). Site Acquisition Costs listed are the portion of lease expenses for the full term of the lease, allocated by square footage as follows: 790 square feet for the PET/CT area, divided by 6,133 square feet in the entire leased space. The applicant states that the proposed project will not incur financing costs. JRC has entered into a service agreement with CDL Nuclear Technologies, LLC, such that capital expenses, including the facility renovations, will be paid using operating revenues. Should the proposed project be approved, the applicant anticipates that it will be operational December 16, 2028.

⁷ Bateman et.al. American Society of Nuclear Cardiology and Society of Nuclear Medicine and Molecular Imaging Joint Position Statement on the Clinical Indications for Myocardial Perfusion PET. Journal of nuclear cardiology (2016): official publication of the American Society of Nuclear Cardiology. <https://pubmed.ncbi.nlm.nih.gov/27528255/> (accessed December 17, 2024).

Table 3. Capital Costs, JRC, Establish Cardiac PET/CT Service

Direct Construction Cost	\$ 256,000
Equipment not included in construction contract	\$ 824,000
Site Acquisition Costs	\$ 88,085
Architectural & Engineering fees	\$ 10,000
Total Capital Cost	\$ 1,178,085

Source: COPN Request No. VA-8885, Completeness Response

Project Definition

Section 32.1-102.1:3 of the Code of Virginia defines a project, in part, as the “[e]stablishment of a medical care facility described in subsection A.” A medical care facility includes “[a]ny specialized center or clinic or that portion of a physician's office developed for the provision of ...[or] positron emission tomographic (PET) scanning...”

Required Considerations -- §32.1-102.3, of the Code of Virginia

In determining whether a public need for a project exists, the following factors shall be considered:

- 1. The extent to which the proposed project will provide or increase access to health care services for people in the area to be served and the effects that the proposed project will have on access to health care services in areas having distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to health care;**

The proposed project is in Salem, where the population in both this locality and PD 5 is decreasing. The growth rate of the population segment aged 65 and over in Salem is projected to be 18.7%, with the city expected to add 997 people in this age group between 2020 and 2030 through aging and in-migration. This rate of growth in the older population is comparable to PD 5's at 18.3% but far lower than Virginia's at 30.9% (**Table 1**). The proposed site is near the intersection of Keagy Road and Electric Road (US Route 419) with convenient access to Interstate 81. Ample on-site parking is available, including handicapped parking. For individuals who rely on public transportation, Valley Metro provides fixed-route and para transit service in the Roanoke/Salem metropolitan area.

With respect to socioeconomic barriers, the poverty rate of PD 5 (12.3%) is higher than that of Virginia (10.7%) (**Table 4**). The City of Salem, the location of the proposed project, has a 10.4% poverty rate, more comparable to Virginia's poverty rate.

Table 4. PD 5 Poverty Rates, 2024

Geographic Name	Poverty Rate
Alleghany County	13.9%
Botetourt County	6.3%
City of Covington	17.7%
Craig County	12.3%
Roanoke County	7.2%
City of Roanoke	18.4%
City of Salem	10.4%
PD 5	12.3%
Virginia	10.7%

Source: https://www.census.gov/data-tools/demo/saige/#/?s_state=51&s_county=&s_district=&s_geography=county

The applicant states that the two existing PET services in the PD are located within hospitals and do not offer dedicated a PET scanner dedicated to cardiac services for myocardial perfusion imaging. The applicant proposes to improve access to the recommended and preferred modality for myocardial perfusion imaging (cardiac PET/CT scanning) to its patients by transitioning appropriate SPECT imaging volumes to the proposed PET/CT scanner.

2. The extent to which the proposed project will meet the needs of people in the area to be served, as demonstrated by each of the following:

(i) the level of community support for the proposed project demonstrated by people, businesses, and governmental leaders representing the area to be served;

DCOPN received five letters of commitment from JRC cardiologists to staff the proposed PET service, and three letters of support for the proposal from JRC and AlignedCardio physicians. In aggregate, these letters communicate that the proposal is a “meaningful and necessary evolution” in how JRC cardiologists evaluate and manage patients, and it improves clinical decision making, to the benefit of patients. PET/CT technology will help identify patients that will benefit from invasive procedures and help avoid unnecessary procedures. Access to cardiac PET/CT is limited in the area. Offering this modality in an established cardiology practice promises to produce higher quality images with reduced radiation exposure for patients and to close a gap in advanced cardiovascular testing in the region.

Public Hearing

§32.1-102.6B of the Code of Virginia directs DCOPN to hold one public hearing on each application in the case of competing applications, or in response to a written request by an elected local government representative, a member of the General Assembly, the Commissioner, the applicant, or a member of the public. COPN Request No. VA-8885 is not competing with another project, and DCOPN did not receive a request to conduct a public hearing for the proposed project. Thus, no public hearing was held.

DCOPN provided notice to the public regarding this project, inviting public comment on May 8, 2026. The public comment period closed on June 22, 2026. Other than the letters referenced

above, no members of the public commented. There is no documented opposition to the proposed project.

(ii) the availability of reasonable alternatives to the proposed project that would meet the needs of the people in the area to be served in a less costly, more efficient, or more effective manner;

Authorizations for cardiac PET/CT scanners have increased in Virginia in the past several years. These scanners are primarily operated by individual cardiology practices and are generally used for their own patients. PET/CT is developing into a significant technology for cardiac diagnostics. It is the preferred and recommended modality for myocardial perfusion by the American Society of Nuclear Cardiology and the Society of Nuclear Medicine and Molecular Imaging, replacing SPECT as the standard of care.

The status quo entails travel for JRC patients to access a higher-cost, hospital-based PET/CT with cardiac imaging capabilities or continued use of SPECT imaging for myocardial perfusion, which is currently offered at JRC's office site. PET/CT is superior to SPECT in diagnostic accuracy, ability to accurately risk-stratify patients with a wide array of clinical presentations, short acquisition times, safety by virtue of low radiation exposure, and its unique ability to quantify myocardial blood flow. JRC has SPECT patients and a patient base that would benefit from access to the superior, recommended imaging modality for myocardial perfusion. The proposed project is more beneficial than the status quo. No reasonable alternative is identified that serves the population in a less costly, more efficient or more effective manner. Because the applicant proposes to use the PET/CT unit primarily to serve its existing patient population, shifting from SPECT scans to PET/CT scans, and because it will be limited to cardiac use, DCOPN concludes that the proposed project is unlikely to adversely affect the utilization and efficiency of existing services.

(iii) any recommendation or report of the regional health planning agency regarding an application for a certificate that is required to be submitted to the Commissioner pursuant to subsection B of § 32.1-102.6;

Currently, there is no organization in HPR III designated by the Virginia Department of Health to serve as the Health Planning Agency for PD 5. Therefore, this consideration does not apply to the review of the proposed project.

(iv) any costs and benefits of the proposed project;

The projected capital costs of the proposed project are \$1,178,085 (**Table 3**), funded by way of a contract with CDL Nuclear technologies. The contract will be paid from ongoing revenues from the provision of cardiac PET/CT services, such that no financing costs will be incurred. Some similar projects authorized in the past year, in which physician practices established cardiovascular PET services, had capital costs of \$1.3 million (COPN No. VA-04949 issued to James River Cardiology), \$3.8 million (COPN No. VA-04930 issued to Virginia Heart) and \$3.8 million (COPN No. VA-04919, also issued to Virginia Heart). DCOPN concludes that when compared to similar projects, the capital costs of the proposed project are reasonable.

The applicant identified numerous benefits of the proposed project, including access to the preferred and recommended imaging modality for myocardial perfusion in a lower-cost, outpatient setting. PET/CT is superior to SPECT in its image quality, higher diagnostic accuracy and confidence in diagnostic conclusions, and reduced radiation dose for both patients and staff. The applicant asserts that there is no existing dedicated cardiac-specific PET/CT imaging available in the PD. JRC states that by addressing geographic, transportation and access-related barriers, the proposal will expand availability of advanced cardiac diagnostics and improve patient outcomes through earlier and more accurate diagnosis.

(v) the financial accessibility of the proposed project to the people in the area to be the financial accessibility of the proposed project to the people in the area to be served, including indigent people; and

JRC asserts that its practice participates in all major insurance plans and Medicare, ensuring broad accessibility to its services. The proforma provided by the applicant (**Table 5**) estimates charity care contributions of 1.3%, which is above the last published HPR III charity care average.

Table 5. Proforma, JRC, Establish PET/CT Service

	Year 1	Year 2
Gross Revenue	\$2,745,953	\$2,883,251
Charity Care	\$35,697	\$37,482
Other Expenses	\$1,127,981	\$1,162,354
Operating Expenses	\$1,163,678	\$1,199,836
Estimated Profit	\$1,582,275	\$1,683,415

Source: COPN Request No. VA-8885

In accordance with Section 32.1-102.4.B of the Code of Virginia, should the proposed project receive approval, it will be conditioned to provide a level of charity care based on gross patient revenues derived from PET/CT imaging that is no less than the equivalent average for charity care contributions in HPR III in 2024, the latest year for which such data are available. According to regional and statewide data regularly collected by VHI, the average amount of charity care provided by HPR III facilities in 2024 was 0.5% of gross patient revenue (**Table 6**).

Table 6. HPR III Charity Care Contributions: 2024

HPR III	Gross Pt Rev	Total Charity Care Provided Below 200%	%
Inpatient Facilities			
Rehabilitation Hospital of Bristol, LLC	21,074,983	594,048	2.8%
Centra Specialty Hospital	49,629,337	1,151,183	2.3%
Carilion Franklin Memorial Hospital	291,774,472	4,126,513	1.4%
Carilion Tazewell Community Hospital	97,063,289	1,035,463	1.1%
Carilion Medical Center	5,523,913,586	43,089,656	0.8%
Carilion New River Valley Medical Center	1,045,584,847	8,284,749	0.8%
LewisGale Hospital-Montgomery	1,028,863,817	8,035,905	0.8%
Carilion Giles Memorial Hospital	241,763,245	1,965,594	0.8%
Lewis-Gale Medical Center	3,633,204,645	25,020,978	0.7%
LewisGale Hospital Pulaski	557,969,215	3,462,675	0.6%
LewisGale Hospital - Alleghany	307,838,577	1,894,786	0.6%
Bedford Memorial Hospital	220,261,406	1,156,200	0.5%
Johnston Memorial Hospital	939,082,042	3,526,000	0.4%
Centra Health	3,572,261,352	12,125,268	0.3%
Wellmont Lonesome Pine Mountain View Hospital	852,382,429	2,640,163	0.3%
Smyth County Community Hospital	216,722,529	604,993	0.3%
Lee County Community Hospital	43,608,193	118,721	0.3%
Dickenson Community Hospital	28,200,560	54,209	0.2%
Russell County Medical Center	137,892,582	161,769	0.1%
Buchanan General Hospital	127,118,204	137,889	0.1%
Sovah Health-Danville	1,253,164,239	288,678	0.0%
Sovah Health-Martinsville	917,943,082	268,214	0.0%
DLP Twin County Regional Healthcare	363,954,973	128,136	0.0%
Clinch Valley Medical Center	829,913,180	191,054	0.0%
Wythe County Community Hospital	415,798,563	100,166	0.0%
Ridgeview Pavilion (Bristol Region)	8,928,438	0	0.0%
Total Inpatient Hospitals:			26
HPR III Total Inpatient \$ & Mean %	\$ 22,725,911,785	\$ 120,163,010	0.5%

Source: VHI (2024)

Should the proposal be approved, DCOPN recommends that it be conditioned to provide the proffered 1.3% charity care. Pursuant to the Code of Virginia language, any COPN issued for this project will also be conditioned on the applicant's agreement to accept patients who are the recipients of Medicare.

- (vi) **At the discretion of the Commissioner, any other factors as may be relevant to the determination of public need for a project.**

DCOPN notes that no stationary PET scanner in the Commonwealth achieved the SMFP standard of 6,000 PET scans in 2024. The average PET procedures per scanner in Virginia in 2024 was 2,372. DCOPN has previously acknowledged that the SMFP's utilization standards for PET/CT services are outdated and that expecting a PET service to reach the threshold suggested by the SMFP amounts to a misconception about the utilization of this modality at the time the SMFP

was written and should be treated as such. DCOPN recommends that the Commissioner use discretionary authority and, in this specific instance, not allow this standard to bar the addition of a dedicated cardiac PET/CT scanner in PD 5.

3. The extent to which the proposed project is consistent with the State Health Services Plan;

Section 32.1-102.2:1 of the Code of Virginia calls for the State Health Services Plan Task Force to develop recommendations for a comprehensive State Health Services Plan (SHSP). In the interim, DCOPN will consider the consistency of the proposed project with the predecessor of the SHSP, the State Medical Facilities Plan (SMFP).

The SMFP contains criteria/standards for the establishment of PET services. They are as follows:

Part II

Diagnostic Imaging Services

Article 4 Criteria and Standards for Positron Emission Tomography

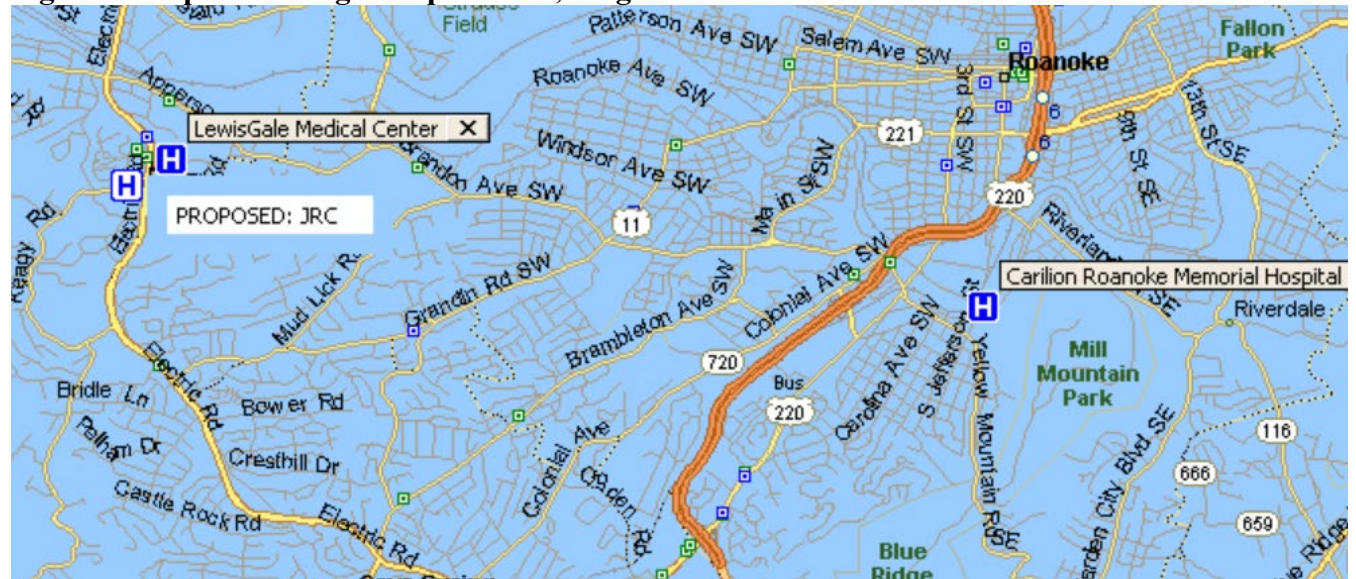
12VAC5-230-200. Travel Time.

PET services should be within 60 minutes driving time one way under normal conditions of 95% of the health planning district using a mapping software as determined by the commissioner.

The heavy black line in **Figure 2** is the boundary of PD 5. The blue “H” symbols mark the locations of the two existing fixed PET providers in PD 5, while the white “H” symbol marks the proposed project. In **Figure 2**, the symbol marking the proposed site covers the locator of the existing PET scanner at LewisGale Medical Center. **Figure 3** shows more clearly the locations of the three sites. The proposed project is 0.5 miles/4 minutes from LewisGale Medical Center and 6 miles/18 minutes from Carilion Roanoke Memorial Hospital. The blue shaded area includes the area that is within 60 minutes driving time one-way under normal conditions of existing PET services in PD 5. **Figure 2** shows that Alleghany County and part of Craig County do not have access to PET services within a 60 minute drive. Though it is a rural county, Alleghany represents more than 5% of PD 5’s population (**Table 1**), so the SMFP travel time standard is not met. DCOPN notes that the SMFP does not distinguish between cardiac-restricted and general diagnostic PET.

A detailed map of the Shenandoah National Park area in Virginia. The park's boundary is highlighted with a thick black line. Major roads, including US-219, US-60, US-130, US-501, US-460, and US-29, are shown in orange. The map also displays various towns and cities such as Frankford, Lewisburg, Fort Spring, Ronceverte, Sweet Springs, Union, Simonsville, Mount Tabor, Blacksburg, Shawsville, Christiansburg, Riner, Radford, Fairlawn, New River, Falling Spring, Covington, Clifton Forge, Iron Gate, Kerrs Creek, Lexington, South River, Buena Vista, Glasgow, Apple Orchard Mountain, Peaksville, Lynchburg, Forest, Bedford, Salem, Roanoke, Cave Spring, Hollins, Cloverdyke, Daleville, Catanya, New Castle, Fincastle, Amsterdam, Buchanan, and Rocky Mount. The map also shows the locations of Jefferson National Forest, Alleghany National Forest, and the Shenandoah River. The state of Virginia is labeled in the center, and surrounding states like West Virginia, Kentucky, and Tennessee are partially visible.

Figure 3. Map of Existing PET providers, Magnified to Visualize all Sites



Source: DCOPN Records, Microsoft Streets and Trips

12VAC5-230-210. Need for New Fixed Site Service.

A. If the applicant is a hospital, whether free-standing or within a hospital system, 850 new PET appropriate cases shall have been diagnosed and the hospital shall have provided radiation therapy services with specific ancillary services suitable for the equipment before a new fixed site PET service should be approved for the health planning district.

The applicant is not a hospital.

B. No new fixed site PET services should be approved unless an average of 6,000 procedures per existing and approved fixed site PET scanner were performed in the health planning district during the relevant reporting period and the proposed new service would not significantly reduce the utilization of existing fixed site PET providers in the health planning district. The utilization of existing scanners operated by a hospital and serving an area distinct from the proposed new service site may be disregarded in computing the average utilization of PET units in such health planning district.

Note: For the purposes of tracking volume utilization, an image taken with a PET/CT scanner that takes concurrent PET/CT images shall be counted as one PET procedure. Images made with PET/CT scanners that can take PET or CT images independently shall be counted as 1 individual PET procedure and CT procedure respectively, unless those images are made concurrently.

Fixed PET providers in PD 5 performed an average of 1,759 procedures per scanner in 2024, or 29.3% of the SMFP standard of 6,000 average procedures per unit in the PD (**Table 2**).

Calculated Needed Fixed PET Scanners in PD 5

Current COPN authorized fixed PET scanners in PD 5 = 3

Calculated Needed Fixed PET scanners = $5,277 \div 6,000 = 0.88$ (1) scanner needed

PD 5 Calculated Need = 1 PET scanner

PD 5 Calculated Surplus = 3 authorized PET scanners– Calculated Need (1) = **Surplus of 2**

There is a calculated surplus of 2 PET scanners in PD 5. DCOPN notes that every PET provider operational in 2024 in PD 5 had less than 40% of the 6,000-procedure threshold required for expansion. DCOPN has previously acknowledged that the SMFP's utilization standards for PET/CT services are outdated and that expecting a PET service to reach the threshold suggested by the SMFP amounts to a misconception about the utilization of this modality at the time the SMFP was written and should be treated as such. DCOPN has previously recommended approval for PET services even though the PD did not meet the SMFP threshold for expansion.

According to VHI data for 2024, the average number of PET procedures performed across all PET providers in the Commonwealth was 2,372. DCOPN notes that the SMFP makes no distinction between unrestricted PET services and specialty-restricted PET services, such as the proposed PET service restricted to cardiovascular imaging. The applicant expects to convert 924 of its current SPECT procedures to PET in its first year of operation and will additionally offer cardiac PET to its patients who were previously not suitable candidates for SPECT.

Due to the distinct nature of the patient base, JRC's ability to convert its own SPECT patients to the superior PET imaging, and the restricted scope of the PET/CT service to only cardiovascular procedures, DCOPN does not anticipate that approval of the proposed project would negatively affect utilization of other PET services in PD 5. Instead, approval of the proposed project would create an overall improvement in access to cardiovascular PET for JRC's patients. While the applicant does not meet the computational analysis of this SMFP standard, DCOPN recommends that the Commissioner, in this specific instance, not allow this standard to bar the establishment of this cardiac PET/CT service.

12VAC5-230-220. Expansion of Fixed Site Services.

Proposals to increase the number of PET scanners in an existing PET service should be approved only when the existing scanners performed an average of 6,000 procedures for the relevant reporting period and the proposed expansion would not significantly reduce the utilization of existing fixed site providers in the health planning district.

The applicant is not proposing to expand an existing fixed-site PET service, so this standard does not apply.

12VAC5-230-230. Adding or Expanding Mobile PET or PET/CT Services.

A. Proposals for mobile PET or PET/CT scanners should demonstrate that, for the relevant reporting period, at least 230 PET or PET/CT appropriate patients were seen and that the proposed mobile unit will not significantly reduce the utilization of existing providers in the health planning district.

B. Proposals to convert authorized mobile PET or PET/CT scanners to fixed site scanners should demonstrate that, for the relevant reporting period, at least 1,400 procedures were performed by the mobile scanner and that the proposed conversion will not significantly reduce the utilization of existing providers in the health planning district.

The applicant is not proposing to add or expand an existing mobile PET/CT service, so this standard does not apply.

12VAC5-230-240. Staffing.

PET services should be under the direction or supervision of one or more qualified physicians. Such physicians shall be designated or authorized by the Nuclear Regulatory Commission or licensed by the Division of Radiologic Health of the Virginia Department of Health, as applicable.

The applicant asserts that the proposed PET service will be under the direction and supervision of qualified physicians appropriately authorized and licensed.

Eight Required Considerations Continued

- 4. The extent to which the proposed project fosters institutional competition that benefits the area to be served while improving access to essential health care services for all people in the area to be served;**

The proposed project does not foster institutional competition. Its primary use will be PET imaging of the applicant's existing cardiac patient base, converted from its SPECT service, a modality that is inferior to PET imaging for myocardial perfusion.

- 5. The relationship of the proposed project to the existing health care system of the area to be served, including the utilization and efficiency of existing services or facilities;**

JRC has cardiovascular practices across Virginia. At its Salem location, its physicians and advanced practice providers cover all aspects of cardiac care, performing comprehensive evaluation, preparation and diagnostic testing in their office. Procedures that require hospital facilities, such as structural heart interventions, cardiac catheterizations, and other advanced procedures, are performed in local hospitals.

- 6. The feasibility of the proposed project, including the financial benefits of the proposed project to the applicant, the cost of construction, the availability of financial and human resources, and the cost of capital;**

Total capital costs of the proposed project are \$1,178,085 (**Table 3**) to be funded through a contract with CDL technologies which the applicant will pay from ongoing revenues. These costs are reasonable when compared to recently approved, similar projects. The pro forma income statement provided by the applicant (**Table 5**) projects a net income of approximately \$1.6 million in the first year of operation and \$1.7 million in the second year of operation. The proposal will require four additional full-time equivalent staff members to operationalize, an attainable recruitment.

- 7. The extent to which the proposed project provides improvements or innovations in the financing and delivery of health care services, as demonstrated by (i) the introduction of new technology that promotes quality, cost effectiveness, or both in the delivery of health care services; (ii) the potential for provision of health care services on an outpatient basis; (iii) any cooperative efforts to meet regional health care needs; and (iv) at the discretion of the Commissioner, any other factors as may be appropriate;**

The proposed project would provide improvements in the delivery of health care services by providing access to the latest, most accurate cardiac imaging technology at a lower cost, in an outpatient setting. Additionally, as there is a limited number of providers of cardiac PET/CT scanning services in PD 5, the proposed project provides access for JRC's existing patient base. DCOPN did not identify any other factors to bring to the Commissioner's attention.

8. In the case of a project proposed by or affecting a teaching hospital associated with a public institution of higher education or a medical school in the area to be served, (i) the unique research, training, and clinical mission of the teaching hospital or medical school and (ii) any contribution the teaching hospital or medical school may provide in the delivery, innovation, and improvement of health care services for citizens of the Commonwealth, including indigent or underserved populations.

Not applicable. The applicant is not affiliated with a teaching hospital associated with a public institution of higher education or a medical school in the area to be served.

DCOPN Staff Findings and Conclusions

The population in PD 5 is decreasing, and the 65 and older population, which has a higher risk of heart conditions, is growing in PD 5 at a much slower rate than it is across Virginia. DCOPN finds James River Cardiology, LLC d/b/a AlignedCardio's request to establish a center for PET/CT services with one fixed PET/CT scanner restricted to cardiovascular imaging in Salem, Virginia to be generally consistent with the applicable criteria and standards of the SMFP and the Eight Required Considerations of the Code of Virginia. The proposed project improves access for the applicant's patients to the preferred and recommended imaging modality for myocardial perfusion. The proposal establishes the first outpatient (lower cost) PET/CT service in the PD. It is unlikely that approval of COPN Request No. VA-8885 will reduce volumes of existing PD 5 providers significantly, given that the applicant has existing SPECT imaging volumes, some of which will convert to PET/CT procedures.

There is no alternative identified to the proposed project that is less costly, more efficient and more effective than the proposed project. Furthermore, it is more beneficial than the status quo. The proposal is wholly feasible in the immediate and long term. There is no documented opposition to the proposed project.

DCOPN Staff Recommendation

The Division of Certificate of Public Need recommends the **conditional approval** of James River Cardiology, LLC d/b/a AlignedCardio's COPN Request No. VA-8885 to establish a center for PET imaging with one PET/CT scanner restricted to cardiovascular imaging, for the following reasons:

1. James River Cardiology, LLC d/b/a AlignedCardio's proposal is generally consistent with the applicable standards and criteria of the State Medical Facilities Plan and the 8 Required Considerations of the Code of Virginia.
2. The applicant's existing patient base and proposed cardiovascular restriction make it unlikely that the proposal will negatively impact existing providers.
3. There is no alternative identified to the proposed project, and it is more beneficial than the status quo.

4. Projected costs are reasonable, and the proposal is wholly feasible.
5. There is no known opposition to the proposed project.

DCOPN's recommendation is contingent upon James River Cardiology, LLC d/b/a AlignedCardio's agreement to the following charity care condition:

Recommended Condition

James River Cardiology, LLC d/b/a AlignedCardio will provide cardiovascular PET/CT services to all persons in need of these services, regardless of their ability to pay, and will provide as charity care to all indigent persons free services or rate reductions in services and will facilitate the development and operation of primary medical care services to medically underserved persons in PD 5 in an aggregate amount equal to at least 1.3% of James River Cardiology, LLC d/b/a AlignedCardio's gross patient revenue derived from PET/CT services. Compliance with this condition will be documented to the Division of Certificate of Public Need annually by providing audited or otherwise appropriately certified financial statements documenting compliance with the preceding requirement.

James River Cardiology, LLC d/b/a AlignedCardio will provide PET/CT services to individuals who are eligible for benefits under Title XVIII of the Social Security Act (42 U.S.C. § 1395 et seq.), Title XIX of the Social Security Act (42 U.S.C. § 1396 et seq.), and 10 U.S.C. § 1071 et seq. James River Cardiology, LLC d/b/a AlignedCardio will facilitate the development and operation of primary and specialty medical care services in designated medically underserved areas of the applicant's service area.